

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO ETHICON WAVE 4 MOTIONS</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DEFENDANTS' REPLY TO OPPOSITION TO MOTION TO EXCLUDE  
CERTAIN GENERAL OPINIONS OF JERRY BLAIVAS, M.D.**

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (hereinafter "Ethicon") submit this reply in further support of their motion to exclude certain general opinions of Jerry G. Blaivas, M.D.

**PRELIMINARY STATEMENT AND OBJECTION**

In support of their opposition to Ethicon's motion, Plaintiffs have filed excerpts of a deposition that they took of Dr. Blaivas (without Ethicon's counsel present) on August 29, 2016, and they make numerous references to the deposition in their opposition. *See* Doc. 3758 & Ex. A thereto. According to Plaintiffs, Ethicon "blithely ignores and fails to cite" that deposition in its brief. *Id.* at 2. In fact, Plaintiffs blithely ignore that Ethicon moved to strike that deposition, because Plaintiffs did not properly serve notice of that deposition and the deposition is otherwise improper. Doc. 2984. For the reasons set forth in Ethicon's briefing supporting that motion, which is pending, the Court should disregard all references to that improper deposition. *See* Doc. 2985, 3098.

Accordingly, Ethicon will not address in this reply the improper argument made by Plaintiffs in their response that is based on the August 29, 2016 deposition, and the Court should

disregard and reject all such argument. Even if the Court were to consider the deposition, Plaintiffs have not refuted Ethicon's arguments and have not shown that Dr. Blaivas's opinions meet the reliability standard set forth in *Daubert*.

## **LEGAL ARGUMENT**

### **I. The Court should preclude Dr. Blaivas from testifying that TVT Devices are not safe in the treatment of SUI.**

#### **A. Dr. Blaivas's opinions about TVT Devices are premised on an unreliable assessment of complications and complication rates.**

Plaintiffs' opposition to Ethicon's challenge of Dr. Blaivas's opinions about TVT Device complications is supported by nothing more than Dr. Blaivas's improper August 29, 2016 *ex parte* deposition and other information that was not timely provided in his expert report. Even aided by the improper deposition, Plaintiffs still have not provided any explanation as to how Dr. Blaivas came up with the minimum 12.5% complication rate. Essentially all Dr. Blaivas has stated is that he somehow came up with the figure after reviewing a number of studies, but he cannot explain the methodology.

Plaintiffs also make no attempt to deny that Dr. Blaivas's opinions in this case about pain and dyspareunia are inconsistent with his own 2015 review article, which calculated that only 1.8% of retropubic mesh (like TVT) patients have pain more than six weeks postoperatively. Ex. H to Doc. 2038, Sept. 2015 Dep., Ex. 4, p. 5.

#### **B. Dr. Blaivas has employed a different standard in the courtroom.**

In any event, the Court should preclude Dr. Blaivas from testifying that TVT Devices are not safe in the treatment of SUI, because Plaintiffs' opposition completely ignores Ethicon's argument that Dr. Blaivas has employed a different standard in the courtroom than he does in his practice. Citing *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at \*15 (S.D. W. Va. May 5, 2015), Defendants have argued that the Court should preclude Dr. Blaivas from testifying

that certain sling devices are not safe in the treatment of SUI because he admitted that he utilizes a different standard for medical literature than he employs when providing opinions in litigation. *See* Doc. 2822, pp. 7-8. *See also Flores-Banda v. Boston Scientific Corp.*, 2016 U.S. Dist. LEXIS 60984, at \*34-35 (S.D. W. Va. May 9, 2016).

Throughout this litigation, the Court has consistently and appropriately found that a party waives arguments that it chooses not to address in its response. *See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500766, at \*3 (S.D. W. Va. Aug. 26, 2016) (granting Ethicon's motion to exclude certain expert testimony and noting that "[t]he plaintiffs do not respond to the MSDS-related objections, and the court will not make arguments for them"). Accordingly, the Court should grant Ethicon's motion and preclude Dr. Blaivas from testifying that TVT Devices are unsafe for the treatment of SUI.

## **II. The Court should preclude Dr. Blaivas from testifying that traditional surgical approaches are a safer alternative to the devices at issue.**

In their initial brief, Defendants noted that Dr. Blaivas's opinions that TVT Devices present a heightened risk of complications as compared to autologous slings are based solely on his own personal experiences. In response, Plaintiffs assert that Dr. Blaivas's opinions are further supported by the medical literature. Doc. 3758, p. 13. Yet, Dr. Blaivas has acknowledged that the medical literature on autologous slings is "poor." Ex. H to Doc. 2038, Blaivas Sept. 2015 Dep. 97:20-98:5. According to Dr. Blaivas: "[M]y opinion for safety is based not only on the medical literature, which I've already said I think when it comes to safety is poor, by my review on what's not in the literature. So I suppose in a sense that's a review of the literature. So, I'm going to say, yes, it is based on the medical literature." *Id.* at 404:18-24.

Such an opinion is hopelessly unreliable. Thus, the question becomes whether Dr. Blaivas's personal experiences alone are sufficient to satisfy the rigors of *Daubert* scrutiny.

However, it is unreliable for Dr. Blaivas to base his opinions on a comparison of the experiences of his own autologous sling patients, alone, with the experiences of other physicians' synthetic sling patients.

The fatal fallacy of Plaintiff's logic is illustrated in the following hypothetical: Suppose TaylorMade and Titleist are engaged in a lawsuit, and an issue involves which company's golf ball travels farther. The proof shows that the industry driving average (averaging both pro and semi-pro golfers) for Titleist golf balls is 250 yards, which is greater than the TaylorMade average. TaylorMade seeks to present as an expert witness Dustin Johnson, who testifies as follows: "I have never hit Titleist golf balls. I don't know how far most golfers drive TaylorMade golf balls, but I know that I drive TaylorMade golf balls an average of 300 yards. Because I personally drive TaylorMade golf balls farther than the Titleist industry average, it is my expert opinion that TaylorMade golf balls travel farther than Titleist golf balls." This would be junk science.

### **III. The Court should preclude Dr. Blaivas from testifying that other synthetic mesh devices offer safer alternatives.**

#### **A. Dr. Blaivas is not qualified.**

Plaintiffs offer no explanation as to why the Court should depart from its prior rulings determining that Dr. Blaivas is not competent to provide design opinions. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561 (S.D. W. Va. 2014); *Wilkerson*, 2015 WL 2087048, at \*15; *Flores-Banda*, 2016 U.S. Dist. LEXIS 60984, at \*35-36. Further, Plaintiffs ignore that they objected to deposition questions about Dr. Blaivas's design opinions as being "beyond the scope" and that Dr. Blaivas, himself, testified that "I hadn't ever thought about [sharing design opinions] in public." Ex. H to Doc. 2038, Sept. 2015 Dep. 129:4-12. Thus, Plaintiffs may not now seek to "slip in" such opinions.

**B. Dr. Blaivas's weight/pore size opinions are unreliable.**

Plaintiffs do not dispute that Dr. Blaivas is unwilling to stand behind any other synthetic mesh devices as being safer feasible alternatives to TVT. Nor have Plaintiffs identified any studies demonstrating that lighter weight, larger pore mesh is safer than and as effective as TVT Devices.

**C. Dr. Blaivas's opinions about the cutting of TVT Device mesh are unreliable.**

Conspicuously absent from Plaintiffs' response and from Dr. Blaivas's report is the citation to one single article in the scientific literature or a single test that supports his opinions about the cutting of mesh. Given the lack of any reliable foundation for his opinions and Dr. Blaivas's failure to stand behind either cutting of the mesh as a suitable alternative, the Court should preclude him from opining about this topic. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 712-13 (S.D. W. Va. 2014).

**D. Dr. Blaivas's opinions about TVT implantation design are unreliable.**

According to Plaintiffs, Dr. Blaivas's criticisms of the TVT "bottom to top" approach is supported "in the literature." Doc. 3758, p. 18. Yet, Plaintiffs' response does not cite any literature or other scientific data that supports his opinions. His opinions are unreliable and should be excluded.

**E. Dr. Blaivas's opinions about the size of surgical trocars are unreliable.**

Notwithstanding Plaintiffs' suggestion that "literature" supports his criticisms of the size of the surgical trocars used for TVT implantation, Plaintiffs do not provide any of this alleged literature in support of their opposition. Doc. 3758, p. 19. Plaintiffs offer no explanation as to why the Court should depart from its finding in the Wave 1 cases that Dr. Blaivas's opinions on this topic are unreliable. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, at \*4 (S.D. W. Va. Aug. 26, 2016).

**F. Dr. Blaivas's opinions about TVT-O and TVT-Abbrevio are unreliable.**

Plaintiffs do not identify a single study supporting Dr. Blaivas's criticisms of TVT-O in Section II.5 of his TVT-O report and his criticisms of TVT Abbrevio set forth in Section II.32 of that report. Ex. C & F to Doc. 2038. These opinions are wholly unreliable and should be excluded.

**IV. The Court should exclude Dr. Blaivas's product warning opinions.**

Plaintiffs have offered no reason for the Court to depart from its Wave 1 ruling that "Dr. Blaivas does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re: Ethicon*, 2016 WL 4500767, at \*4.

**V. The Court should limit Dr. Blaivas's biomaterials opinions, such as testimony about alleged mesh degradation, shrinkage, and other deformations.**

In their opposition, Plaintiffs take a position completely different than Dr. Blaivas. Although Dr. Blaivas has conceded that "the biochemistry and stuff was over my head" and that "I think experts that are more expert at this than me should look into this in more depth" (Ex. U to Doc. 2038, 1/30/14 Dep. 482:12-13, 484:17-19), Plaintiffs ask that the Court find that Dr. Blaivas did not really mean what he said under oath. As in *Tyree* and *Huskey*, the Court should find that Dr. Blaivas is not competent to render biomaterials opinions. 54 F. Supp. 3d at 562; 29 F. Supp. 3d at 722.

Even if Plaintiffs could somehow show that Dr. Blaivas is qualified to provide biomaterials opinions, Plaintiffs have ignored Ethicon's argument in its initial brief that these opinions should also be excluded because they are unreliable. *See* Doc. 2822, pp. 18-19.

**VI-X. The Court should preclude Dr. Blaivas from providing other opinions which Ethicon has challenged.**

In their opposition, Plaintiffs do not appear to oppose the arguments set forth in Sections VI-X of Ethicon's initial brief. Accordingly and for the reasons set forth in Ethicon's initial

brief, the Court should preclude Dr. Blaivas from testifying about: (a) inflammatory and irrelevant alleged conditions; (b) testing; (c) alleged “industry manipulation”; (d) Prolene Soft; (e) Ethicon’s alleged knowledge and conduct; (f) facts parroted from corporate documents; and (g) Ethicon’s alleged marketing tactics.

### CONCLUSION

For the foregoing reasons and those set forth in Defendants’ initial brief, Defendants respectfully request that the Court limit Dr. Blaivas’s trial testimony in these cases.

Respectfully Submitted,

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
(601) 985-4523  
[Christy.jones@butlersnow.com](mailto:Christy.jones@butlersnow.com)

/s/ David B. Thomas

David B. Thomas (W. Va. Bar #3731)  
Thomas Combs & Spann PLLC  
300 Summers Street  
Suite 1380 (25301)  
P.O. Box 3824  
Charleston, WV 25338  
(304) 414-1807  
[dthomas@tcspllc.com](mailto:dthomas@tcspllc.com)

Counsel for Defendants Ethicon, Inc.,  
Ethicon LLC, and Johnson & Johnson

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
(601) 985-4523  
christy.jones@butlersnow.com